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510(k) Summary of Safety and Effectiveness
ArthroCare Corporation
ArthroCare® Urology Electrosurgery System

General Information

Manufacturer:
ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94085-2936

Establishment Registration Number: 2951580

Contact Person:
Betty M. Johnson
Manager, Regulatory Affairs

Date Prepared: February 23, 2001

Device Description

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Trade Name: ArthroCare® Urology Electrosurgical System

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

ArthroCare Bipolar Loop Electrosurgical System — K955531

Intended Uses

The ArthroCare Urology Electrosurgery System is a bipolar electrosurgical device intended for use in patients requiring endoscopic surgery for general urological procedures. Urological tissue can be resected using this System, such as the prostate, in procedures including transurethral prostatectomy (TURP) and transurethral incisions in the prostate (TUIP), as well as non-malignant tumors of the bladder wall. The System has been shown to be effective in tissue resection, ablation, and excision, as well as in hemostasis of blood vessels. It is intended for endoscopic procedures using saline solution, Ringer's lactate, or other conductive solutions as irrigants, under direct or video-assisted fiberoptic visualization.

Product Description

The ArthroCare Urology Electrosurgery System is a bipolar, high frequency electrosurgical system consisting of three components: an electrosurgical generator called the Controller, a disposable bipolar Loop, and a reusable Loop Cable.

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Substantial Equivalence

This Special 510(k) proposes a modification in the performance specifications, dimensional specifications, materials, and labeling for the Controller and Loop components of the ArthroCare Urology Electrosurgery System, which was previously cleared in K955531 on February 21, 1996. The indications for use, the principles of operation, the packaging materials, and the sterilization parameters of the ArthroCare Urology Electrosurgery System remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The proposed modifications to the Controller and Loop components of the ArthroCare Urology Electrosurgery System, as described in this submission, are substantially equivalent to the predicate device. The proposed modification in performance specifications, dimensional specifications, materials, and labeling specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2001

Ms. Betty Johnson
Manager, Regulatory Affairs
ArthroCare® Corporation
595 North Pastoria Avenue
SUNNYVALE CA 94085

Re: K010568
ArthroCare® Bipolar Loop Electrosurgery System
Modified Performance Specifications, Dimensional Specifications, Materials, and Labeling
Dated: February 23, 2001
Received: February 26, 2001
Regulatory Class: II
21 CFR §876.4300/Procode: 78 KNS and FAS

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications Statement

Device Name: ArthroCare® Urology Electrosurgery System

510(k) Number: K010568

Indications for use:

The ArthroCare Urology Electrosurgery System is a bipolar electrosurgical device intended for use in patients requiring endoscopic surgery for general urological procedures. Urological tissue can be resected using this System, such as the prostate, in procedures including transurethral prostatectomy (TURP) and transurethral incisions in the prostate (TUIP), as well as non-malignant tumors of the bladder wall. The System has been shown to be effective in tissue resection, ablation, and excision, as well as in hemostasis of blood vessels. It is intended for endoscopic procedures using saline solution, Ringer's lactate, or other conductive solutions as irrigants, under direct or video-assisted fiberoptic visualization.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-the-Counter Use	____

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010568